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| APPLICATION NO.                | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------|-------------|----------------------|---------------------|------------------|
| 10/810,649                     | 03/29/2004  | Mark R. Burns        | 22116-00002-US2     | 3790             |
| 30678                          | 7590        | 05/03/2005           | EXAMINER            |                  |
| CONNOLLY BOVE LODGE & HUTZ LLP |             |                      | DESAI, RITA J       |                  |
| SUITE 800                      |             |                      | ART UNIT            | PAPER NUMBER     |
| 1990 M STREET NW               |             |                      |                     |                  |
| WASHINGTON, DC 20036-3425      |             |                      | 1625                |                  |

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/810,649             | BURNS ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Rita J. Desai          | 1625                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 3-5,11-29 and 31 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,7,30,32,33 and 33 is/are rejected.
- 7) Claim(s) 6 and 8-10 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/2005, 1/2005, 7/</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____.                                    |

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**DETAILED ACTION**

Claims pending 1-33.

***Election/Restrictions***

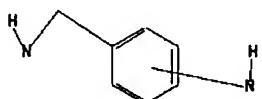
Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 6-10 ,29 in part , drawn to compounds and composition wherein the compound has the formula as given in Claim 3 , classified in class 564, 514 subclass 336, 649. A species of example Q in the table 1 was further elected. This was elected in the parent application.
- II. Claims 4, 6-10, 31, in part, drawn to compounds and compositions wherein the compound has the formula as given in claim 4 ( heterocyclic ring with one N) wherein n is 2 or 3, classified in class 546, 548, 514 and various subclasses.
- III. Claims 5-10 in part , drawn to compounds and composition of a different structure as give in claim 5 ( atleast 2 aromatic rings), classified in class 564, 514 and various subclasses.
- IV. Claims 1,2, 6-10, 30,32 , 33 in part , drawn to compounds and compositions of the formula given in claim 1 and 2 wherein R1 and R are both hydrogen, classified in class 564, 514 subclass 336, 649. A species of claim 32 structure T was further elected.
- V. Claims 11-29 , drawn to methods of treating , classified in class 514 and various subclasses.
- VI. Claims 1-10 in part drawn to compounds wherein R1 and R are not hydrogens. A further election of a single disclosed species is required.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have a different core and hence different bonding and properties.

A preliminary search of the core did not run to completion and gave numerous iterations. See below:-



=> s11

SAMPLE SEARCH INITIATED 11:53:50 FILE 'REGISTRY'

SAMPLE SCREEN SEARCH COMPLETED - 152460 TO ITERATE

0.7% PROCESSED 1000 ITERATIONS 32 ANSWERS

INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE \*\*INCOMPLETE\*\*

BATCH \*\*INCOMPLETE\*\*

PROJECTED ITERATIONS: EXCEEDS 1000000

PROJECTED ANSWERS: EXCEEDS 93388

Thus the core is not applicants contribution over the prior art .

The groups are hence independent and distinct inventions.

Also when a search was done with R not being a hydrogen it lead to an incomplete search.

Inventions I-IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case there are numerous drugs which are used to treat cell proliferation conditions, viral, bacterial or fungal diseases , arthritis, diabetes and such.

Inventions I to II, I to III and.I to IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions The compounds have a different core and hence bonding and properties. The different groups with the different cores are **patentably independent and distinct**. A 102 reference on one would not render obvious another group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and the **search required for Group I is not required for Group II-V**, restriction for examination purposes as indicated is proper. The **search is burdensome** to the PTO.

A telephone call was made to Mr. Amernick on 4/ 25/05 to request an species. A preferred species of example structure T in table I or compound of claim 32 was elected and it is encompassed in group IV of the restriction.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicant 's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art , the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants preserve their right to file a divisional on the canceled non-elected claims , without prejudice in due course.

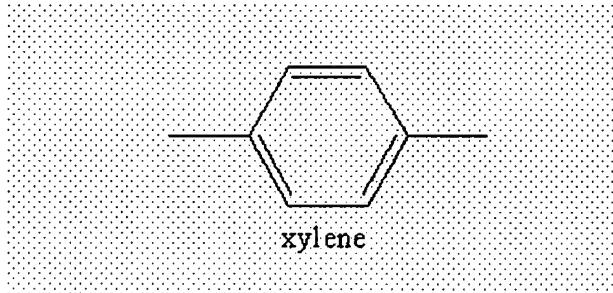
The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1 , 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that the polyamine is a non-symmetrical xylene.

This is not clear.



Xylene is given by [REDACTED] and has no amine group. Thus xylene cannot be a polyamine.

Clarification and correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the pharmaceutical composition, does not reasonably provide enablement for compositions that would be useful in inhibiting cell growth. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claim does not clearly explain how it would be modified to treat cell growth. Or proliferation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is a hybrid claim since it drawn to a pharmaceutical composition and also a method of using it.

The examiner has treated it as a pharmaceutical composition claim.

### ***Claim Objections***

Claim 30, 31 and 33 are also objected to since they refers to a figure.

Applicants are required to insert the compound structure into the claims.

### ***Conclusion***

The claims are otherwise allowable over the prior art of record.

If applicants amend the claims to the elected group wherein R and R1 are both H and overcome the 112 issues given above the claims will be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai  
Primary Examiner  
Art Unit 1625

R.D.  
April 28, 2005

